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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,283	02/11/2004	John F. Shanley	P067	5462

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EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,283	SHANLEY ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27,29,31-44 and 48-51* is/are pending in the application.

4a) Of the above claim(s) *38-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27,29,31-37 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 3/15/2007, has been received. Claims 21 – 27, 29, 31 – 44 and 48 – 51 are pending, and claims 38 – 44 and 45 – 50 are withdrawn as non-elected. Claims 1 – 27, 29, 31 – 37, and 48 are discussed on the merits below.

Response to Arguments

Applicants' arguments have been fully considered, and are persuasive. The rejections detailed in the office action mailed 11/15/2006 are **withdrawn**.

The following rejections are necessitated by newly discovered prior art.

Priority

It is noted that Applicants' claim priority to US Patent Application 10/402,893, now US Patent No. 7,056,338. However the '893 Application (and '338 Patent) do not support a priority claim. Specifically, the '338 patent does not support the genus of "wherein the concentration of the at least one therapeutic agent in the matrix varies as a continuous gradient relative to a surface of the body of the implantable medical device". The '338 patent only supports the sub-genus wherein the concentration in the later applied layer (that is, the outermost layer) is smaller than that of the inner layer (col. 13, lines 5 – 21, claims 1 – 3). Instant claims may have a greater concentration on the outside than the inside.

Since the claims are not fully supported by the priority document, the effective filing date of instant Application is **2/11/2004**. As such, US 2004/0073294 to Diaz et al. and US 2003/0068355 to Shanley et al. are competent references under 35 USC 102(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21 – 27, 29, 31 – 37, and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 12 of U.S. Patent No. 7,056,338. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are generic as to the direction of the concentration gradient (that is, the greater concentration may be either on the inner or outer portion of the stent), whereas the patented claims only apply to concentration gradients wherein the greater concentration is on the interior of the stent. As such, copending claims are a species of instant genus claims, thus rendering the entire species of instant claims obvious. Note that copending claims refer to "holes" whereas instant claims refer to "recesses". However, the '383 patent defines holes as

including recesses (see col. 7, lines 42 – 43), so the two terms are understood to be commensurate or at least overlapping in scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "a miscible organic solvent". However it is not clear what the organic solvent is miscible with. Thus, the artisan would not understand the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21 – 27, 29, 31 – 37, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Shanley et al., US 2003/0068355 ('355 or the '355 reference).

The '355 reference clearly discloses the method of instant claims. See examples 2 – 5.

Note that although there are two common inventors, the inventive entity of instant Application is different from that of copending application, and the '355 reference is therefore a competent reference under 35 U.S.C. 102(e).

Claims 21 – 34, 27, 29, 32, 33, 36, 37, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0073294 ('294 or the '294 reference).

The '294 reference teaches a method of making a stent by adding beneficial agent to recesses in the body of the stent (figures 1, 2 and descriptions thereof, paragraphs 0038 – 0041). The beneficial agent is added from a solution with a polymer binder (PLGA) and DMSO as the solvent (paragraphs 0091 – 0093), which solidifies by evaporation of solvent. The first layer (paragraphs 0091) has no therapeutic agent, and is equivalent to the dissolution barrier of instant claim 34). In some embodiments, there is a second, capping layer on top of the therapeutic agent containing layer, the capping layer containing no therapeutic agent (paragraphs 0046 and 0093) commensurate with instant claim 35. Generally, the therapeutic agent is added in successive layers (paragraphs 0040 – 0045, figure 2 and description thereof) in order to impart a concentration gradient to the final product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21 – 27, 29, 31 – 37, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,624,411 to Tuch in view of US 5,707,385 to Williams.

The teachings of Tuch have been discussed previously.

What is lacking is a teaching of filling recesses with the drug-containing polymer matrix.

Williams teaches an improved method for forming stents, and stents formed thereby. Williams teachings include forming a sheath for a stent that encircles the stent body, the sheath having recesses or holes (abstract, figures 9 – 13 and description thereof). This configuration is advantageous because it increases the artisan's ability to control the release and diffusion rate of the drug from the stent (col. 6, lines 41 – 57). The drug is placed in the stent by making a drug-polymer matrix in a solution, and

loading the matrix into the recesses, and then solidifying the drug-polymer mixture (col. 11, lines 35 – 49, col. 2, lines 30 – 40, col. 9, lines 55 – 67, col. 10, lines 49 – 67).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the method of Tuch (involving sequential addition of drug-polymer solutions with different drug concentrations) to add drug to the sheathed-stent of Williams. The motivation comes from both Tuch and Williams, who each teach the advantages of their particular methods in controlling the release of the drug. Tuch achieves a near zero-order release rate by layering, and Williams achieves easy control over the release duration by loading the drug in recesses. The artisan would thus expect the combination to achieve a controlled, near zero order release rate and an easy control over the duration of release. Since Williams' sheathed stent is loaded in a manner very similar to that of Tuch (that is, by application of a drug-polymer solution), the artisan would enjoy a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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